Remarks/Arguments

Claims 6-22, 24-43, and 45-50 are pending. Claims 6-12, 19-22, 24-40, and 46-50 were withdrawn by the Office in an Office Action dated April 18, 2005 as drawn to non-elected subject matter. Applicants present the following remarks to address the concerns expressed in the final Office Action dated August 10, 2007.

Claims 13-18, 41-43, and 45 stand rejected under 35 U.S.C. § 102 (a), (b), and/or (e) as allegedly anticipated by U.S. publication No. 2003/0036554 to Avrutov et al. ("'554 publication"), U.S. patent No. 6,723,852 to Maimo ("'852 patent"), U.S. patent No. 4,758,579 to Kohl et al. ("'579 patent"), and Kohl, et al., *J. Med. Chem.*, 1992, 35, pp. 1049-1057 ("Kohl article"). Applicants respectfully traverse.

Each one of claims 13-18, 41-43, and 45 encompasses a "crystalline solid pantoprazole" having a particular powder x-ray diffraction ("PXRD") pattern and/or a particular infrared ("IR") pattern or a pharmaceutical composition thereof. As previously argued, none of the '554 publication, the '852 patent, the '579 patent, or the Kohl article discloses the recited PXRD and/or IR patterns. *See, e.g.*, Amendment dated September 5, 2006, p. 10; Amendment dated May 29, 2007, pp. 7-10. Thus, none of the cited references discloses each and every recitation of the claims, as is required for anticipation. *See, e.g., Motorola Inc. v. Interdigital Technology Corp.*, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997).

In addition, Applicants have prepared pantoprazole according to the processes disclosed in Example 11 of the '554 publication and Example 18 of the '852 patent and believe to have found that these processes do not produce the crystalline solid pantoprazole having the characteristics recited in the claims. Applicants will submit a Rule 132 declaration including the experimental data to support this assertion shortly.

In view of the foregoing arguments, the rejection of claims 13-18, 41-43, and 45 under 35 U.S.C. § 102(a), (b), and/or (e) as anticipated by the '554 publication, the '852 patent, the '579 patent, and the Kohl article cannot stand and should be withdrawn.

Claims 13-18, 41-43, and 45 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over the '554 publication, '852 patent, '579 patent, and the Kohl article, in view of the secondary references U.S. patent No. 6,384,059 ("'059 patent"), U.S. publication No. 2004/0177804 ("'804 publication"), Haleblian, et al., *J. Pharm. Sci.*, 1969, 58, pp. 911-929 ("Haleblian"), Muzaffar, et al., *J. Pharmacy*, 1979, 1(1), pp. 59-66 ("Muzaffar"), Rouhi, *Chem. & Eng'g News*, Feb. 2003, pp. 32-35 ("Rouhi"), U.S. PHARMACOPEIA, 1995, pp. 1843-

1844 ("USP 1995"), Jain, et al., *Indian Drugs*, 1986, 23(6), pp. 315-329 ("Jain"), Taday, et al., *J. Pharm. Sci.*, 2003, 92(4) ("Taday"), Brittain, et al., POLYMORPHISM IN PHARMACEUTICAL SOLIDS, 183-286 (Marcel Dekker 1999) ("Brittain"), and Concise Encyclopedia Chemistry, 1993, pp. 872-873 ("Encyclopedia"). Applicants respectfully traverse.

The essence of the Office's argument in support of the obviousness rejections has been that a new polymorphic form of a known compound is rendered obvious by the prior art disclosure of the compound itself in combination with the general disclosure of polymorphism. The Office states:

> Again, Avrutov et al., Maimo, and Kohl et al. I, II teach the crystal forms of the instant known compound and as well as the pharmaceutical compositions...Loqvist et al. and Finkelstein et al. specifically teach that the instant compounds and analogous omeprazole are known to exist in additional crystalline forms. Haleblian et al., Muzaffar et al., Jain et al., Brittain et al. and Taday et al. teach that compounds exist as polymorphs. Chemical & Engineering News, Muzaffar et al., US Pharmacopia [sic] and Concise Encyclopedia teach that at any particular temperature and pressure, only one crystalline form is thermodynamically stable. Hence the claimed crystalline form as well as its relative selectivity of properties *vis-à-vis* the known compound are suggested by the references. It would appear obvious to one skilled in the art in view of the references that the instant compound would exist in different polymorphic forms. No unexpected or unobvious properties are noted.

Office Action dated August 10, 2007, p. 5.

As discussed above, the primary references do not "teach the crystal forms of the instant known compound as well as the pharmaceutical compositions."

Further, the general disclosure of polymorphism in the secondary references, when coupled with the disclosure of the compound pantoprazole itself, is not legally sufficient to render obvious the recited polymorphs of pantoprazole because the reasoning for the combination or guidance for the modifications is lacking. As discussed in detail in the Amendment dated May 29, 2007, the Board of Patent Appeals and Interferences has repeatedly reversed rejections of claims to polymorphs as obvious based on this rationale. *See* Amendment dated May 29, 2007, pp. 11-12 and its Attachments A and C to E (citing *Ex parte Havens*, Appeal No. 2001-0091, 2003 WL 21279863 (Bd. Pat. App. & Interf.); *Ex parte Gala*, Appeal No. 2001-0987, 2002 WL 851814, *3 (Bd. Pat. App. & Interf.); *Ex parte*

Meisel, Appeal No. 2002-0438, 2002 WL 32334598 (Bd. Pat. App. & Interf. October 10, 2002); and *Ex parte Polniaszek*, Appeal No. 2001-1805, 2003 WL 22282265 (Bd. Pat. App. & Interf.). The Office, however, cavalierly dismisses these Board decisions by simply stating: "Applicants merely provide Board decisions that reversed the examiner. The decisions are not persuasive because the allowance on one case has no bearing at all on another case." Office Action dated August 10. 2007, p. 6. On the contrary, Applicants discussed the legal and factual grounds for withdrawing such rejection, which have yet to be rebutted.

For these reasons, the rejection of the claims under 35 U.S.C. § 103(a) cannot stand and should be withdrawn.

Claims 41-43 and 45 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking in written description. Applicants respectfully traverse.

The Office again maintains its previous boilerplate written description rejection, alleging that the application lacks written description because "there is a lack of description as to whether the pharmaceutical carriers are able to maintain the compound in the polymorphic form claimed," "[t]he specification fails to describe the pharmaceutical compositions claimed in terms of their x-ray diffraction pattern or infrared spectrum data," and "the specification has...not described how the polymorph forms and compositions being claimed will be maintained and prevented from converting to other forms when used in the *treatment of diabetes mellitus and any and all unknown conditions associated therewith.*" Office Action, pp. 7-9 (emphasis added).[1] In response, Applicants rely on their previous arguments set forth on pages 15 to 18 of the Amendment dated September 5, 2006 and on pages 15 to 16 of the Amendment dated May 29, 2007, hereby incorporated by reference.

As argued in detail on pages 15 to 18 of the Amendment dated September 5, 2006, requiring Applicants to describe how the crystalline forms in the recited pharmaceutical compositions will be maintained and prevented from converting to other forms when used to treat disease in a patient means that the Office is improperly reading temporal limitations into the claims, *i.e.*, a requirement that the crystalline solid pantoprazole maintain its crystallinity

[1] As previously noted in the Amendment dated May 29, 2007, pantoprazole is described in the specification as being used for the inhibition of gastric acid secretion, and not for the treatment of diabetes mellitus as suggested by the Office. *See* Specification, p. 6, l. 31 to p. 7, l. 1. The fact that the Office Action yet again recites the treatment of diabetes mellitus is further evidence of the "boilerplate" nature of the written description rejection.

through formulation, administration, absorption, metabolism, and excretion of the pharmaceutical composition. The claims recite no such temporal limitations. The specification adequately describes the recited compositions when the claims are properly read in accordance with their plain meaning. Accordingly, the rejection of the claims under 35 U.S.C. § 112, first paragraph as lacking written description cannot stand and should be withdrawn.

In addition, Applicants note that the Office again considers the factors set forth by *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) in discussing its written description rejection and states that "[t]aking the...factors into consideration, it is not seen where the instant claim is *enabled* by the instant application." Office Action dated August 10, 2007, p. 12 (emphasis added). The enablement requirement, however, is separate and distinct from the written description requirement of 35 U.S.C. § 112. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991); M.P.E.P. § 2163(I). Therefore, it is improper for the Office to treat written description and enablement as a single basis for rejection. Applicants respectfully request clarification of whether the Office is making a separate enablement rejection.

Claims 13-18, 41, and 45 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly failing to particularly point out and distinctly claim the invention. Applicants respectfully traverse.

The Office asserts that the claims are indefinite because they "contain the generic name pantoprazole." Office Action dated August 10, 2007, p. 13. The Office states that "[w]here a generic name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph" because "the name pantoprazole does not properly identify the chemical structure of the compound." *Id.*

As previously argued on pages 17 to 18 of the Amendment dated May 29, 2007, one of ordinary skill in the art would have readily recognized the term "pantoprazole" as a shorthand chemical name for the compound 5-(difluoromethoxy)-2-[[3,4-dimethoxy-2-pyridinyl)methyl] sulfinyl]-1H-benzimidazole at the time the application was filed. *See Merck Index*, 13th ed., p. 1256, compound 7084 (2001). Further, the term pantoprazole is explicitly defined in the specification as "5-(difluoromethoxy)-2-[[3,4-dimethoxy-2-pyridinyl)methyl] sulfinyl]-1H-benzimidazole." Specification, p. 1, ll. 15-17. Because one of ordinary skill in the art would understand the metes and bounds of the claim term pantoprazole when it is read in light of the specification, the claims meet the requirements of

35 U.S.C. § 112, second paragraph. Thus, the Applicants should not be required to include the IUPAC chemical name or chemical structure of pantoprazole in the claims, as the Office suggests.

For these reasons, the rejection of claims 13-18, 41, and 45 under 35 U.S.C. § 112, second paragraph cannot stand and should be withdrawn.

In view of the foregoing remarks, Applicants respectfully submit that the claims are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same.

Respectfully Submitted,

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